

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:) Examiner: Angela Marie Hoffa
Thomas KOEHLER et al.)
Serial No.: 10/598,004) Art Unit: 3768
Filed: May 10, 2007) Confirmation No.: 8994
February 15, 2005)
as PCT/IB2005/050576)
For: **DRUG APPLICATION**)
DURING A CT SCAN)
Attorney Docket: PHDE040056US) Cleveland, Ohio 44143

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir / Madam:

This Appeal Brief is being filed in regard to the final rejection of the patent application identified above.

CERTIFICATE OF ELECTRONIC TRANSMISSION

I certify that this **APPEAL BRIEF** in connection with U.S. Serial No. 10/598,004 is being filed on the date indicated below by electronic transmission with the United States Patent and Trademark Office via the electronic filing system (EFS-Web).

Dec. 15, 2010
Date

Patricia A. Heim
Patricia A. Heim

I. REAL PARTY IN INTEREST

The real party in interest concerning this application is Koninklijke Philips Electronics N.V., having an address at Groenenwoudseweg 1, Eindhoven, Netherlands 5621 BA. That company is the assignee of record as indicated in the assignment recorded at Reel/Frame No. 019276/0059.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

As discussed in more detail in the next section, the final amendments to the claims in this application before appeal were made via an “Amendment B” filed on June 10, 2010. Thus a total of 20 claims have been presented for consideration. The current status of those 20 claims is that claims 1-10 and 12-20 remain pending and are on appeal at this time. The remaining claim, claim 11, has been canceled and so is not on appeal.

IV. STATUS OF AMENDMENTS

The final amendments to the claims in this application were made via an “Amendment B” filed on June 10, 2010. It is the claims as presented in that amendment which are being appealed. There has, however, been some confusion concerning the communications following the August 2, 2010 Final Office Action rejecting all pending claims. The following explanatory remarks are therefore provided.

Following the August 2, 2010 Final Office Action, Examiner Hoffa graciously agreed to conduct an telephonic Interview on October 6, 2010. While some consensus was reached which resulted in withdrawal of a new matter rejection under 35 U.S.C. § 112, the prior art rejections were maintained. It was agreed that the applicant would provide further arguments in an After-Final Communication for consideration by the Examiner.

Therefore, on October 15, 2010, the applicant filed three different papers: an After-Final Communication, a Notice of Appeal, and a Pre-Appeal Brief Request for Review. The After-Final Communication, which contained a listing of the pending claims, did not make any

amendments to the claims. It merely re-presented the claims as finally amended on June 10, 2010 for the convenience of the reader and provided some remarks concerning the interview. On October 19, 2010, the Examiner initially refused to consider the Pre-Appeal Brief Request for Review on the basis that the After-Final Communication was an amendment. Upon a request for reconsideration, pointing out that no amendments were made in the After-Final Communication, the Examiner relented and the requested pre-appeal brief review was conducted. However, that review did not result in any change of position by the USPTO in this application, and so the applicant is filing this Appeal Brief.

V. SUMMARY OF CLAIMED SUBJECT MATTER

In this section the applicant provides a summary of the claimed subject matter of the independent claims on appeal, as well as each dependent claim argued separately.

Independent claim 1 recites a method of controlling a local application of drugs to a part of a body of a patient during a CT scan. See Application, at Figure 3 and page 11, lines 17-25. According to the claimed method, the drugs are transported S2 in containers 30 suitable for introduction into a bloodstream of the patient, including a first drug transported in a first container. See id.; see also id. at page 8, lines 5-17 and page 9, line 1 to page 11, line 16. The containers prevent an application of the drugs. See id. A heart beat rate of the patient is monitored S5 during the CT scan. See id. at page 11, lines 26-27. The first container is ruptured S7 in proximity to the part of the body on the basis of the monitored heart beat rate S5, resulting in a local application S8 of the first drug to the part of the body and a controlled change S9 of the heart beat rate of the patient to reduce variations in the heart beat rate during the CT scan. See id. at page 11, line 26 to page 12, line 18.

Claim 5 depends from claim 1. It adds to the method of claim 1 the transportation of a second drug in a second container. The first container has a first resonance frequency, and the second container has a second resonance frequency. The first resonance frequency is different from the second resonance frequency. See id. at page 9, lines 7-17; page 10, line 4 to page 11, line 5; and page 11, line 26 to page 12, line 6.

Claim 6 depends from claim 5. It further specifies to the method of claim 5 that application of the first drug increases the heart beat rate, and application of the second drug

decreases the heart beat rate. See id. at page 9, lines 7-17; page 10, line 4 to page 11, line 5; and page 11, line 26 to page 12, line 6.

Independent claim 8 recites a CT scanner system adapted for controlling a local application of drugs to a part of a body of a patient 7 during a CT scan. See id. at Figure 1 and page 6, line 24 to page 8, line 19. The CT scanner system comprises a CT scanner; a monitoring device 29; a data processing device 18 or 27; and a destruction device 23. See id.; see also Figure 2 and page 8, line 20 to page 9, line 6. The drugs are transported in containers 30 suitable for introduction into a bloodstream of the patient 7 and preventing an application of the drugs. See id. at page 8, lines 5-17 and page 9, line 1 to page 11, line 16. The CT scanner is adapted for acquisition of an image of the part of the body, and the monitoring device 29 is adapted for monitoring a heart beat rate of a heart of the patient during the CT scan. See description of claim 1, supra. The destruction device 23 is adapted for rupturing a first container 30 in proximity to the part of the body, resulting in a local application of a first drug to the part of the body and a controlled change of the heart beat rate of the patient to reduce variations in the heart beat rate during the CT scan. See description of claim 1, supra. The data processing device 18 or 27 is adapted for triggering the rupturing of the first container on the basis of the monitored heart beat rate. See description of claim 1, supra.

Claim 15 depends from claim 8. It adds to the CT scanner of claim 8 a second drug transported in a second container, wherein the second drug is different from the first drug. The first container has a first resonance frequency, and the second container has a second resonance frequency. The first resonance frequency is different from the second resonance frequency. See id. at page 9, lines 7-17; page 10, line 4 to page 11, line 5; and page 11, line 26 to page 12, line 6.

Claim 16 depends from claim 15. It further specifies to the CT scanner of claim 15 that application of the first drug increases the heart beat rate, and application of the second drug decreases the heart beat rate. See id. at page 9, lines 7-17; page 10, line 4 to page 11, line 5; and page 11, line 26 to page 12, line 6.

Independent claim 10 recites a computer program for controlling a local application of drugs to a part of a body of a patient during a CT scan. The computer program causes a processor to perform an operation when the computer program is executed on the processor.

According to the operation, a heart beat rate of a heart of the patient is evaluated during the CT scan. A rupturing of a container comprising a drug is triggered on the basis of the evaluation of the heart beat rate. The container is located in proximity to the part of the body, resulting in a local application of the drug to the part of the body and a controlled change of the heart beat rate of the patient to reduce variations in the heart beat rate during the CT scan. See description of prior claims, supra.

Independent claim 18 recites an imaging scanner system. A scanner is adapted for acquiring an image of the heart in an imaging scan. A monitoring device is adapted to monitor a heart beat rate of the patient during the imaging scan. A destruction device is adapted for rupturing a container in proximity to the heart, resulting in a local application of a drug stored in the container and a controlled change of the patient's heart beat rate to reduce variations in the heart beat rate during the imaging scan. A data processing device is adapted for operating the destruction device, based on data received from the monitoring device. See description of prior claims, supra.

Claim 20 ultimately depends from independent claim 18. It adds that the destruction device is adapted to generate pulses having different frequencies in order to rupture containers having different resonance frequencies. See id. at page 9, lines 7-17; page 10, line 4 to page 11, line 5; and page 11, line 26 to page 12, line 6.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following two grounds of rejection, as provided in the Final Office Action dated August 2, 2010, are to be reviewed on appeal:

- (A) The rejection of claims 1-4, 7, 8-9, 10, 12-14 and 17-19 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,397,098 to Uber; and
- (B) The rejection of claims 5-6, 15-16 and 20 under 35 U.S.C. § 103 as being unpatentable over Uber alone.

The third ground of rejection provided in the Final Office Action, a new matter rejection under 35 U.S.C. § 112, has been withdrawn. See USPTO Interview Summary mailed on October 12, 2010.

VII. ARGUMENT

The applicant respectfully requests that the prior art rejections of all pending claims 1-10 and 11-20 be reversed, for the following reasons.

A. Claims 1-4, 7, 8-9, 10, 12-14 and 17-19 Are Not Anticipated by Uber

Claims 1-4, 7, 8-9, 10, 12-14 and 17-19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,397,098 to Uber (“Uber”). Those rejections are improper, for the following reasons. Therefore, it is requested that these rejections be reversed and the claims be allowed.

(1) Claims 1, 2-4 and 7

Independent claim 1 is not anticipated by Uber because Uber fails to disclose the claim limitation reciting a controlled change of the heart beat rate of the patient “to reduce variations in the heart beat rate during the CT scan.” As a result, the rejection of claim 1 as anticipated by Uber should be reversed. For the same reason, the rejections of claim 1’s dependent claims 2-4 and 7 should also be reversed.

As an initial matter, the August 2, 2010 Final Office Action completely ignores the limitation in claim 1 reciting a controlled change of the heart beat rate of the patient “to reduce variations in the heart beat rate during the CT scan.” See August 2, 2010 Final Office Action, at 3 (incomplete analysis of claim 1) and at 4 (relying upon the incomplete analysis of claim 1 in rejecting the other independent claims 8, 10 and 18). The rejection of claim 1 by the August 2, 2010 Final Office Action should be reversed on this basis alone. As the current record stands, the applicant is left to guess at what disclosure in Uber is regarded by the Examiner as disclosing reducing variations in the heart beat rate. Nonetheless, by force of necessity, the applicant’s representative will endeavor to do so.

As set forth in the specification of this pending application, reducing variations in the heart beat rate during a CT scan this has several benefits. These benefits include for example avoidance of motion artifacts or a spatially varying temporal resolution (page 1, lines 16-29), which results in an improved image quality (page 5, lines 25-27). Uber fails to disclose this claim limitation, for at least the following reasons.

Uber discloses the control of an appropriate dose of contrast agent during a medical imaging procedure. See Uber, col. 1, lines 12-40 and col. 2, lines 21-45. The contrast agent functions to enhance the contrast of the images generated by the imaging apparatus, such as an ultrasound apparatus. See Uber, col. 7, lines 17-65. According to Uber, vasodilator and vasoconstrictor drugs are administered during ultrasound cardiac stress echo imaging in conjunction with a heart rate monitor, so that when the heart rate reaches a target level the contrast agent injection process is initiated, terminated or adjusted, or scanner settings are adjusted. See Uber, col. 10, lines 25-65 and col. 10, line 66 to col. 11, line 21. The portion of Uber cited by the Examiner as disclosing “a controlled change of the heart beat rate” is one example of that general disclosure, in which the target heart rate level may be determined to more easily image tissue perfusion levels via imaging of the contrast agent flowing through the tissue. See *id.* at col. 13, line 66 to col. 8, line 8 and at col. 14, line 65 to col. 15, line 21.

Thus, Uber discloses applying vasodilator and vasoconstrictor drugs while monitoring a patient’s heart beat rate during an imaging scan to achieve a target heart beat rate. However, it does not disclose reducing variations in a heart beat rate. Rather, Uber simply discloses that once the target heart beat rate is achieved then one or more of the imaging system or contrast agent injection parameters is initiated, terminated or adjusted. Uber entirely fails to disclose continued monitoring of the heart beat rate after the target heart beat rate is achieved. So far as the disclosure in Uber is concerned, reaching the target rate triggers a change in contrast agent injection or scanner settings — but that is all Uber discloses. Uber never discloses attempting to reach a target heart beat rate and, once achieved, reducing variations in the heart beat rate in an attempt to keep it steady.

The essential difference between Uber and claim 1 is that Uber discloses a “one-way” driving mechanism, wherein the heart beat rate is driven to reach the target by either speeding up (if the current rate is less than the target rate) or slowing down (if the current rate is greater than the target rate). Importantly, once the target rate is first achieved in a one-way drive, Uber does not disclose continuing thereafter to apply drugs to change the heart beat rate. In substantial contrast, claim 1 is directed to a “two-way” driving mechanism by requiring reducing variations in the heart beat rate. Once a desired heart beat rate is achieved, claim 1 requires continued monitoring and adjustment as needed in an attempt to keep the heart beat rate constant or at least within pre-determined maximum and minimum values — that is, reduce variations in the heart beat rate. Uber discloses nothing of the sort.

Indeed, at one point in time the Examiner apparently agreed that Uber does not anticipate claim 1. Uber first arose in this application when it was cited in an April 28, 2010 Office Action. That Office Action rejected claim 1 (as it then stood) as anticipated by Uber, but went on to provide the following statement of allowable subject matter despite Uber (reference letters [a] to [e] have been added by the applicant in this quotation):

[a] control of the heart beat rate [b] during the CT scan [c] to be for the purpose of creating a steady heart beat rate during the CT scan [d] in order to reduce variations in heart beat rate of the patient during the CT scan [e] that result in an improved image quality of an image of the patient's heart."

See April 28, 2010 Office Action, at 5. Following that Office Action the applicant amended claim 1 to recite elements [a], [b] and [d] as the essence of the allowable subject matter. See June 10, 2010 Amendment. One topic which was discussed during the October 6, 2010 Interview was whether adding one or both of elements [c] and [e] would make the claims allowable, but the Examiner stated that it would not. In other words, the Examiner withdrew the indication of allowable subject matter. In the applicant's view, the Examiner's initial conclusion on April 28, 2010 was correct: claim 1 as it currently stands is indeed patentable over Uber.

(2) Claims 8-9, 12-14 and 17

Independent claim 8 is not anticipated by Uber because Uber fails to disclose the claim limitation reciting a controlled change of the heart beat rate of the patient "to reduce variations in the heart beat rate during the CT scan." This lack of sufficiency in the disclosure of Uber is discussed above in connection with a corresponding limitation in claim 1. As a result, the rejection of claim 8 as anticipated by Uber should be reversed. For the same reason, the rejections of claim 8's dependent claims 9, 12-14 and 17 should also be reversed. (In preparing this Appeal Brief, the applicant's representative noted that claim 17 should depend from claim 8 rather than claim 1 as it currently stands, to avoid duplication with claim 7.)

(3) Claim 10

Independent claim 10 is not anticipated by Uber because Uber fails to disclose the claim limitation reciting a controlled change of the heart beat rate of the patient "to reduce variations in the heart beat rate during the CT scan." This lack of sufficiency in the disclosure of Uber is discussed above in connection with a corresponding limitation in claim 1. As a result, the rejection of claim 10 as anticipated by Uber should be reversed.

(4) Claims 18-19

Independent claim 18 is not anticipated by Uber because Uber fails to disclose the claim limitation reciting a controlled change of the heart beat rate of the patient “to reduce variations in the heart beat rate during the CT scan.” This lack of sufficiency in the disclosure of Uber is discussed above in connection with a corresponding limitation in claim 1. As a result, the rejection of claim 18 as anticipated by Uber should be reversed. For the same reason, the rejection of claim 18’s dependent claim 19 should also be reversed.

(5) Conclusion

In short, all the anticipation rejections based on Uber should be reversed and the claims allowed because Uber fails to disclose a controlled change of the heart beat rate of the patient “to reduce variations in the heart beat rate during the CT scan.”

B. Claims 5-6, 15-16 and 20 are Not Unpatentable As Obvious Over Uber Alone.

Claims 5-6, 15-16 and 20 stand rejected under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 6,397,098 to Uber (“Uber”) alone. Those rejections are improper, for the following reasons. Therefore, it is requested that these rejections be reversed and the claims be allowed.

First, all the claims in this group ultimately depend from one of the independent claims which were rejected as anticipated by Uber. Thus, the obviousness rejections of these dependent claims should be reversed for the same reason that the anticipation rejections of the parent independent claims should be reversed: Uber fails to disclose the limitation in the parent independent claims reciting a controlled change of the heart beat rate of the patient “to reduce variations in the heart beat rate during the CT scan.”

Second, the specific limitations added by dependent claims 5, 15 and 20 also are not disclosed in Uber, for the following reasons. Those three claims each require that there are two kinds of drug containers injected into the patient, wherein the containers differ in the resonance frequency required to rupture the containers. The Final Office Action (at page 5) concedes this claimed subject matter is not disclosed in Uber. It nonetheless concluded it would be obvious to one of ordinary skill in the art at the time of invention to provide containers with two different

resonance frequencies to selectively apply one or the other of the vasodilator or vasoconstrictor drugs which are disclosed in Uber.

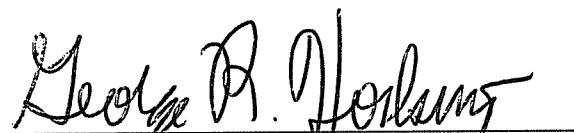
However, as discussed at length above, Uber discloses only a "one-way" driving mechanism whereas the present claims are directed to a "two-way" driving mechanism. In order to achieve the one way result as disclosed in Uber, only one of the two drugs (vasodilator or vasoconstrictor) is required. In substantial contrast, to achieve the two-way result as claimed in the present application, both kinds of drugs are required. Because there is no disclosure in Uber concerning a two-way mechanism, there is nothing in Uber that would make it obvious to use both drugs at once. One or the other of the two drugs is sufficient to achieve Uber's goals, so it would not be obvious to use both kinds of drugs during an imaging scan.

Thus, for the foregoing reasons, dependent claims 5, 15 and 20 are not unpatentably obvious over Uber alone. Claims 6 and 16 further depend, respectively, from claims 5 and 16. Thus, the obviousness rejections of all these claims should be reversed, and the claims allowed.

C. Conclusion

All the pending claims are patentable over the art of record cited in the Final Office Action. The rejections of these claims should therefore be reversed, and the claims allowed.

Respectfully submitted,



George R. Hoskins, Esq.
Calfee, Halter & Griswold LLP
800 Superior Avenue, Suite 1400
Cleveland, Ohio 44114
(216) 622-8200

APPENDIX 1:
LISTING OF CLAIMS

1. A method of controlling a local application of drugs to a part of a body of a patient during a CT scan, wherein the drugs are transported in containers suitable for introduction into a bloodstream of the patient; wherein the containers prevent an application of the drugs; and wherein a first drug is transported in a first container; the method comprising the steps of: monitoring a heart beat rate of the patient during the CT scan; and rupturing the first container in proximity to the part of the body on the basis of the monitored heart beat rate, resulting in a local application of the first drug to the part of the body and a controlled change of the heart beat rate of the patient to reduce variations in the heart beat rate during the CT scan.
2. The method according to claim 1, wherein the part of the body the drugs are locally applied to is the heart of the patient; and wherein the first drug is locally applied to the heart of the patient by rupturing the first container in proximity to the heart.
3. The method according to claim 1, wherein the first container has a first resonance frequency such that when an ultrasonic energy pulse with a first frequency corresponding to the first resonance frequency is applied to the first container, a rupture of the first container occurs and the first drug is released from the first container; wherein the rupturing of the first container is performed by means of a destruction device; wherein the destruction device generates focused ultrasound pulses; and wherein the ultrasound pulses have a first frequency corresponding to the first resonance frequency of the first container.
4. The method according to claim 1, wherein the first container has a first resonance frequency such that when an electromagnetic energy beam with a first frequency corresponding to the first resonance frequency is applied to the first container, a rupture of the first container occurs and the first drug is released from the first container; wherein the rupturing of the first container is performed by means of a destruction device; wherein the destruction device generates a beam of electromagnetic radiation; and wherein the electromagnetic radiation has a first frequency corresponding to the first resonance frequency of the first container.

5. The method according to claim 1, wherein a second drug is transported in a second container; wherein the first container has a first resonance frequency; wherein the second container has a second resonance frequency; and wherein the first resonance frequency is different from the second resonance frequency.

6. The method according to claim 5, wherein the application of the first drug increases the heart beat rate; and wherein the application of the second drug decreases the heart beat rate.

7. The method according to claim 1, wherein the containers are micro-bubbles.

8. A CT scanner system adapted for controlling a local application of drugs to a part of a body of a patient during a CT scan, comprising:

a CT scanner; a monitoring device; a data processing device; and a destruction device; wherein the drugs are transported in containers suitable for introduction into a bloodstream of the patient and preventing an application of the drugs; wherein the CT scanner is adapted for acquisition of an image of the part of the body; wherein the monitoring device is adapted for monitoring a heart beat rate of a heart of the patient during the CT scan; wherein the destruction device is adapted for rupturing a first container in proximity to the part of the body, resulting in a local application of a first drug to the part of the body and a controlled change of the heart beat rate of the patient to reduce variations in the heart beat rate during the CT scan; and wherein the data processing device is adapted for triggering the rupturing of the first container on the basis of the monitored heart beat rate.

9. The CT scanner system according to claim 8, wherein the first drug is locally applied to the heart of the patient on the basis of the heart beat rate; wherein the first container has a resonance frequency; wherein the destruction device is adapted for generating one of focused ultrasound pulses and a beam of electromagnetic radiation; and wherein a frequency of the one of focused ultrasound pulses and the beam of electromagnetic radiation corresponds to the resonance frequency of the first container.

10. A computer program for controlling a local application of drugs to a part of a body of a patient during a CT scan, wherein the computer program causes a processor to perform the following operation when the computer program is executed on the processor: evaluating a heart

beat rate of a heart of the patient during the CT scan; triggering a rupturing of a container comprising a drug on the basis of the evaluation of the heart beat rate; wherein the container is located in proximity to the part of the body, resulting in a local application of the drug to the part of the body and a controlled change of the heart beat rate of the patient to reduce variations in the heart beat rate during the CT scan.

11. (Cancelled).
12. The CT scanner system according to claim 8, wherein the part of the body the drug are locally applied to is the heart of the patient.
13. The CT scanner system according to claim 8, wherein the first container has a first resonance frequency such that when an ultrasonic energy pulse with a first frequency corresponding to the first resonance frequency is applied to the first container, a rupture of the first container occurs and the first drug is released from the first container; wherein the rupturing of the first container is performed by means of a destruction device; wherein the destruction device generates focused ultrasound pulses; and wherein the ultrasound pulses have a first frequency corresponding to the first resonance frequency of the first container.
14. The CT scanner system according to claim 8, wherein the first container has a first resonance frequency such that when an electromagnetic energy beam with a first frequency corresponding to the first resonance frequency is applied to the first container, a rupture of the first container occurs and the first drug is released from the first container; wherein the rupturing of the first container is performed by means of a destruction device; wherein the destruction device generates a beam of electromagnetic radiation; and wherein the electromagnetic radiation has a first frequency corresponding to the first resonance frequency of the first container.
15. The CT scanner system according to claim 8, further comprising a second drug transported in a second container; wherein the second drug is different from the first drug; the first container has a first resonance frequency; the second container has a second resonance frequency; and wherein the first resonance frequency is different from the second resonance frequency.
16. The CT scanner system according to claim 15, wherein application of the first drug increases the heart beat rate, and application of the second drug decreases the heart beat rate.

17. The CT scanner system according to claim 1, wherein the containers are micro-bubbles.

18. An imaging scanner system comprising:

a scanner adapted for acquiring an image of the heart in an imaging scan;

a monitoring device adapted to monitor a heart beat rate of the patient during the imaging scan;

a destruction device adapted for rupturing a container in proximity to the heart, resulting in a local application of a drug stored in the container and a controlled change of the patient's heart beat rate to reduce variations in the heart beat rate during the imaging scan; and

a data processing device adapted for operating the destruction device, based on data received from the monitoring device.

19. The imaging scanner of claim 18 wherein the destruction device generates one of an ultrasound pulse and an electromagnetic radiation pulse in order to rupture the container.

20. The imaging scanner of claim 19 wherein the destruction device is adapted to generate pulses having different frequencies in order to rupture containers having different resonance frequencies.

APPENDIX 2:
EVIDENCE

None.

APPENDIX 3:
RELATED PROCEEDINGS

None.